K014160

FEB 0 8 2002

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:
Debbie Schmitt
Cook OB/GYN
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-6500
December 14, 20001

Device:

Trade Name:	Pre-Implantation Genetic Diagnosis Pipettes (Biopsy Pipettes)
Proposed Classification Name:	Class II Assisted Reproduction Microtools 85MQH
CFR Reference:	884.6130

Predicate Devices:

Cook OB/GYN understands due to the recent reclassification there are no predicate devices. We have used Cook Australia devices as our predicate to illustrate safety and effectiveness.

The Pre-Implantation Genetic Diagnosis Pipettes (Biopsy Pipettes) are substantially equivalent to other pipettes in terms of indications for use, design, construction and material equivalence.

Specifically, these devices are similar to the Pipettes manufactured and distributed in Europe by Cook Australia, 12 Electronics Street, Brisbane Industrial Park, Eight Miles Plains, Queensland, 4113, Australia.

Device Description:
The Pre-Implantation Genetic Diagnosis Pipettes (Biopsy Pipettes) are used for the aspiration of blastomeres for Pre-Implantation genetic diagnosis. These devices are intended for one-time use and will be marketed sterile.

These devices are manufactured entirely from borosilicate glass. Mouse Embryo Toxicity testing and Endotoxin testing have been performed on the borosilicate glass. Results show the material meets the requirements of these tests.

Substantial Equivalence:
This device will be manufactured according to specified process controls and a Quality Assurance Program. Being similar with respect to indications for use, materials and physical construction to predicate devices, these devices meet the requirements for section 510(k) substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 8 2002

Ms. Debbie Schmitt
Regulatory Affairs Manager
COOK® Urological
1100 W. Morgan Street
SPENCER IN 47460

Re: K014160
Trade/Device Name: Pre-Implantation Genetic Diagnosis Pipettes (Biopsy Pipettes)
Regulation Number: 21 CFR §884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: 85 MQH
Dated: December 14, 2001
Received: December 19, 2001

Dear Ms. Schmitt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

COOK®

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PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014160

Device Name: Pre-Implantation Genctic Diagnosis Pipettes
(Biopsy Pipettes)

The Pre-Implantation Genetic Diagnosis Pipettes are used for the aspiration of blastomeres for pre-implantation genetic diagnosis. These devices are intended for one-time use and will be marketed sterile.
"This tool is indicated for embryo or blastomere biopsy, which may be done in order to perform preimplantation genetic diagnosis (PIGD) on the genetic material in the biopsied cell(s). Tests for PGD are currently developed and their performance characteristics are determined by the individual laboratories for their own use. The performance of these tests may vary depending on the particular assay and disease evaluated. Currently these tests have not been cleared or approved by the Food and Drug Administration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014160